

REMARKS

Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested.

I Status Of The Claims

Claims 76-82, 84-88 and 90-93 were pending before entry of this Amendment. New claims 94-98 have been added. Support for new claims 94-98 may be found in the specification, e.g., at page 3, lines 8-9, page 11, lines 5-11, page 14, line 27 to page 15, line 6, page 17, lines 22-23, and in original claims 5-9.

Claims 76-82, 84-88 and 90-98 are pending in this application and are at issue.

II Rejection Under 35 U.S.C. § 112, first paragraph

Claims 76-82, 84-88 and 90-93 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner asserts that these claims recite, or depend upon a claim that recites the negative limitation “a compound that is not phenylalanine, tyrosine and/or tryptophan” and contends that such a limitation does not provide one of ordinary skill in the art with any description of what the Applicant claims as the invention.

This rejection is not believed to be well taken, and is respectfully traversed.

Firstly, contrary to the Examiner’s assertion, claims 82, 84-88 and 90-93 do not recite, or depend upon a claim that recites “a compound that is not phenylalanine, tyrosine and/or tryptophan.” Accordingly, the Applicant believes that the rejection of claims 82, 84-88 and 90-93 was made in error, and respectfully requests that the rejection be withdrawn. Furthermore, new claims 94-98 also do not recite “a compound that is not phenylalanine, tyrosine and/or tryptophan.” Accordingly, the Applicant believes that new claims 94-98 do not lack written description.

Second, the Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant’s disclosure a

description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90 (CCPA 1976). See MPEP § 2163.04. The Applicant submits that the Examiner has failed to meet this burden merely by asserting that the negative limitation does not provide adequate written description.

One of ordinary skill in the art, upon reading the present disclosure, would clearly understand the Applicant had possession, at the time the application was filed, of the method of claim 76, namely a method for treating FMS and/or psychological symptoms associated therewith using an effective amount for treating FMS of milnacipran and an effective amount for treating FMS of an additional compound that is not phenylalanine, tyrosine and/or tryptophan, and claims 77-81 dependent therefrom.

Milnacipran is a well know compound, disclosed at numerous points throughout the specification, for example, for use as an antidepressant. Fibromyalgia syndrome (FMS) is also a well known disorder. One of ordinary skill in the art would readily appreciate what additional compounds could be used in conjunction with milnacipran for treating FMS, as presently claimed in claim 76. The mere recitation of the phrase “a compound that is not phenylalanine, tyrosine and/or tryptophan” does not mean that one of ordinary skill in the art has not been provided with any description of what the Applicant claims as the invention.

Indeed, claim 77 (see also claims 82 and 88) limits the compound administered in combination with milnacipran to an antidepressant, analgesic, muscle relaxant, anorectic, stimulant, antiepileptic drug, sedative, or hypnotic (see the specification at page 11, lines 5-7). These are well-known classes of active agents. Accordingly, one of ordinary skill in the art would readily appreciate suitable antidepressant, analgesic, muscle relaxant, anorectic, stimulant, antiepileptic drug, sedative, or hypnotic compounds that could be used in combination with milnacipran in the method of claim 77. Claim 78 (see also claims 84 and 90) limits the compound administered in combination with milnacipran to the specific compounds neurontin, pregabalin, pramipexole, l-DOPA, amphetamine, tizanidine, clonidine, tramadol, morphine, codeine, carbamazepine, sibutramine, valium, or trazodone (see the specification at page 11, lines 9-11). Therefore, the Applicant clearly had

possession of the invention of claims 77-78 (and claims 82, 84, 88 and 90) at the time the application was filed.

Accordingly, claims 76-82, 84-88 and 90-93 comply with the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection should be withdrawn.

III Rejection Under 35 U.S.C. § 112, second paragraph

Claims 76-82, 84-88 and 90-93 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner asserts that the negative limitation “a compound that is not phenylalanine, tyrosine and/or tryptophan” renders the claims of indeterminate scope.

This rejection is not believed to be well taken, and is respectfully traversed.

Again, the Applicant respectfully points out to the Examiner that claims 82, 84-88 and 90-93 do not recite, or depend upon a claim that recites “a compound that is not phenylalanine, tyrosine and/or tryptophan.” Accordingly, these claims are not indefinite, as asserted by the Examiner, and the rejection should be withdrawn. Furthermore, new claims 94-98 also do not recite “a compound that is not phenylalanine, tyrosine and/or tryptophan.” Accordingly, Applicant believes that these new claims are not indefinite.

Moreover, with respect to claim 76, and claims 77-81 dependent therefrom, the recitation of a negative limitation does not render the metes and bounds of these claims any less ambiguous. The Applicant is simply claiming less than the full scope of their disclosure – a perfectly legitimate exercise since it is for the inventors to decide what bounds of protection they will seek.

The MPEP states that “[t]he current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph” See MPEP § 2173.05(i). See, e.g., *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638., 641 (CCPA 1970) (in which a claim reciting “said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea

rubber” in order to exclude the characteristics of the prior art product was considered definite because each limitation was definite). See also, *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971) (in which the negative limitation “incapable of forming a dye with said oxidized developing agent” was found definite because the boundaries of the patent protection sought were clear).

Applicant submits that the boundaries of claims 76-81 are indeed clear and set forth definitely. As stated above, claims 76-81 recite the well known compound, milnacipran. The requirement of claim 76 that the milnacipran be administered in combination with an additional compound that is not phenylalanine, tyrosine and/or tryptophan, for treatment of FMS, does not render this claim indefinite. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). A broad claim with clear scope complies with 35 U.S.C. §112, second paragraph. See MPEP § 2173.04.

Moreover, as discussed above, claim 77 (see also claims 82 and 88) limits the compound administered in combination with milnacipran to several classes of well known active agents, while claim 78 (see also claims 84 and 90) limits the compound administered in combination with milnacipran to the specific compounds neurontin, pregabalin, pramipexole, l-DOPA, amphetamine, tizanidine, clonidine, tramadol, morphine, codeine, carbamazepine, sibutramine, valium, or trazodone. Accordingly, claims 77 and 78 (as well as claims 82, 84, 88 and 90) are not indefinite.

In view of the above arguments, the Applicant submits that claims 76-82, 84-88 and 90-93 are not indefinite and respectfully requests that the rejection be withdrawn.

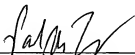
IV Conclusion

No new matter has been added by these amendments. In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. At the very least, claims 82, 84-88 and 90-98 are in condition for allowance. In any event, the Examiner is respectfully requested to enter the Amendment, as it is believed to reduce the number of issues for appeal.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Dated: January 17, 2006

By 
Paul M. Zagar, M.D.
Registration No.: 52,392
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant